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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

JUN 0 6 2013

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   March 8, 2013

6. **TRADE NAME(S):**
   Aquilion PRIME, TSX-303A/2 and 303A/6, v5.00

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography

10. **PERFORMANCE STANDARD:**
    This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

11. **PREDICATE DEVICE:**

Product	Marketed by	510(k) Number	Clearance Date
TSX-302A/2, Aquilion Prime CT System	Toshiba America Medical Systems	K120710	April 6, 2012

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion PRIME TSX-303A/2, v5.00** is an 80-row CT System and the **TSX-303A/6, v5.00** is a 40-row CT system that is intended to produce axial scans of the whole body to include the head. These systems are based upon the technology and materials of previously marketed Toshiba CT systems.

14. SUMMARY OF INTENDED USES:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion Prime has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

15. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the TSX-302A/2, Aquilion Prime CT System, K120710, marketed by Toshiba America Medical Systems. The **Aquilion PRIME TSX-303A/2 and 303A/6, v5.00**, incorporates modifications to the cleared device which include a smaller gantry size, addition of optional software features and new patient couches. The method of operation, base software and manufacturing process remain unchanged from the cleared device.

A complete comparison table is included in this submission. See below for a brief summary of changes from TSX-302A/2, Aquilion Prime CT System:

Item	**Aquilion PRIME TSX-303A/2 and 303A/6, v5.00**	TSX-302A/2, Aquilion Prime CT System
X-ray Tube Substitution X-ray tube capacity Maximum tube cooling rate Continuous tube cooling rate	 7.5 MHU 1386 kHU/min 1008 kHU/min	 7.5 MHU 1386 kHU/min 1008 kHU/min
Gantry Size	W=2150mm, H=1870mm, D=870mm	W=2430mm, H=2030mm, D=1070mm
Gantry Tilt Angle	±30°	±22°
Gantry Scan Switch	Standard	N/A
Lamp for Indication of Breathing	Breath-hold time indication added	N/A

(Continued)

Item	**Aquilion PRIME TSX-303A/2 and 303A/6, v5.00**	TSX-302A/2, Aquilion Prime CT System
Helical Shuttle Scan	Optional	N/A
Lung Volume Analysis	Optional *(Previously cleared under K113715)*	N/A

1. X-ray tube substitution
2. Smaller gantry
3. Increased gantry tilt angle
4. New gantry scan switch and breath-hold indication
5. Previously cleared software options are being added

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-1-9, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18and NEMA XR-25. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

17. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the requirements for the modifications made to the system have been met. The modified system was also evaluated according to an image quality metrics study, utilizing phantoms, which validated that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number and contrast-to-noise ratio and noise properties.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

18. CONCLUSION

The modifications incorporated into the **Aquilion PRIME TSX-303A/2 and 303A/6, v5.00** do not change the indications for use or the intended use of the device. Based upon bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that the subject device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2013

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K130645
Trade/Device Name: Aquilion PRIME TSX-303A/2 and 303A/6, v5.00
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 8, 2013
Received: March 11, 2013

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130645

Device Name: Aquilion PRIME, TSX-303A/2 and 303A/6, v5.00

Indications for Use:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion PRIME has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.
Prescription

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130645